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MEDTRONIC, INC. *v.* LOHR ET VIR

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

No. 95–754. Argued April 23, 1996—Decided June 26, 1996*

Enacted "to provide for the safety and effectiveness of medical devices intended for human use," the Medical Device Amendments of 1976 (MDA or Act) classifies such devices based on the risk that they pose to the public. Class III devices pose the greatest risk and, thus, are subject to a rigorous premarket approval (PMA) process. However, most Class III devices on the market have not been through the PMA process due to two statutory exceptions. Realizing that existing devices could not be withdrawn from the market while the Food and Drug Administration (FDA) completed PMA analyses, Congress included a provision allowing pre-1976 devices to remain on the market without FDA approval until the requisite PMA is completed. The Act also permits devices that are "substantially equivalent" to pre-existing devices to avoid the PMA process until the FDA initiates the process for the underlying device. The FDA uses a "premarket notification" submitted by all manufacturers (§ 510(k) process) to determine substantial equivalence for Class III devices. Petitioner Medtronic, Inc.'s pacemaker is a Class III device found substantially equivalent under the § 510(k) process. Cross-petitioners, Lora Lohr and her spouse, filed a Florida state-court suit alleging both negligence and strict-liability claims in the failure of her Medtronic pacemaker, but Medtronic removed the case to the Federal District Court. That court ultimately dismissed the complaint as having been pre-empted by 21 U. S. C. § 360k(a), which provides that "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the Act]." The Court of Appeals reversed in part and affirmed in part, concluding that the Lohrs' negligent design claims were not pre-empted, but that their negligent manufacturing and failure to warn claims were.

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*Together with No. 95–886, *Lohr et vir* v. *Medtronic, Inc.*, also on certiorari to the same court.

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Held: The judgment is reversed in part and affirmed in part, and the cases are remanded.

56 F. 3d 1335, reversed in part, affirmed in part, and remanded.

JUSTICE STEVENS delivered the opinion of the Court with respect to Parts I, II, III, V, and VII, concluding that the MDA does not pre-empt the Lohrs' common-law claims. Pp. 484–486; 492–502; 503.

(a) While the Court need not go beyond § 360k(a)'s pre-emptive language to determine whether Congress intended the MDA to pre-empt at least some state law, see *Cipollone* v. *Liggett Group, Inc.*, 505 U. S. 504, 517, "the domain expressly pre-empted" by that language must be identified, *ibid.* Interpretation of the text is informed by the assumptions that the States' historic police powers cannot be superseded by a Federal Act unless that is Congress' clear and manifest purpose, *Rice* v. *Santa Fe Elevator Corp.*, 331 U. S. 218, 230, and that any understanding of a pre-emption statute's scope rests primarily on "a fair understanding of *congressional purpose*," *Cipollone*, 505 U. S., at 530, n. 27. Pp. 484–486.

(b) The Lohrs' negligent design claims are not pre-empted. The FDA's "substantially equivalent" determination as well as its continuing authority to exclude a device from the market do not amount to a specific, federally enforceable design requirement that would be affected by state-law pressures such as those imposed here. Since the § 510(k) process is focused on *equivalence*, not safety, substantial equivalence determinations provide little protection to the public. Neither the statutory scheme nor legislative history suggests that the § 510(k) process was intended to do anything other than maintain the status quo, which included the possibility that a device's manufacturer would have to defend itself against state-law negligent design claims. Pp. 492–494.

(c) Section 360k(a) does not pre-empt state rules that merely duplicate the FDA's rules regulating manufacturing practices and labeling. That the state requirements may be narrower than the federal rules does not make them "different" under § 360k. Nor does the presence of a damages remedy amount to an additional or different "requirement"; it merely provides another reason for manufacturers to comply with identical existing federal law "requirements." This view is supported by the regulations of the FDA, to which Congress has delegated authority to implement the MDA. Pp. 494–497.

(d) The Lohrs' manufacturing and labeling claims are not pre-empted. Although the statutory and regulatory language may not preclude "general" federal requirements from ever pre-empting state requirements, or "general" state requirements from ever being pre-empted, it is impossible to ignore its overarching concern that pre-emption occur only

where a particular state requirement threatens to interfere with a specific federal interest. State requirements must be "with respect to" medical devices and "different from, or in addition to," federal requirements. They must also relate "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device," and the regulations provide that state requirements of general applicability are pre-empted only where they have "the effect of establishing a substantive requirement for a specific device." Federal requirements must be "applicable to the device" in question, and, according to the regulations, pre-empt state law only if they are "specific counterpart regulations" or "specific" to a "particular device." The federal manufacturing and labeling requirements at issue reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements. Similarly, Florida's common-law requirements were not specifically developed "with respect to" medical devices and, thus, are not the kinds of requirements that Congress and the FDA feared would impede implementation and enforcement of specific federal requirements. Pp. 497–502.

JUSTICE STEVENS, joined by JUSTICE KENNEDY, JUSTICE SOUTER, and JUSTICE GINSBURG, concluded in Part IV that Medtronic's argument that any common-law cause of action is a "requirement" under § 360k(a) is implausible, for it would grant complete immunity from design defect liability to an entire industry that, in Congress' judgment, needed more stringent regulation. It would take language much plainer than § 360k's text to do that. The word "requirement," which appears to presume that the State is imposing a specific duty upon the manufacturer, would be an odd term to use to indicate the sweeping pre-emption Medtronic urges here. *Cipollone*, 505 U. S., at 521–522, distinguished. The legislation's basic purpose and history entirely support the rejection of such an extreme position. Pp. 486–491.

JUSTICE BREYER concluded that, although the MDA will sometimes pre-empt a state-law tort suit, it does not pre-empt the claims at issue here. First, since the MDA's pre-emption provision is highly ambiguous, Congress must have intended that courts look elsewhere for help as to just which federal requirements pre-empt just which state requirements, as well as just how they might do so. Second, in the absence of a clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect. See *Hillsborough County* v. *Automated Medical Laboratories, Inc.*, 471 U. S. 707, 721. Third, the FDA's regula-

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tions indicate that the FDA does not consider that its requirements pre-empt the state requirements at issue here. Fourth, ordinary principles of "conflict" and "field" pre-emption support the conclusion that plaintiffs' tort claims are not pre-empted. Pp. 503–508.

STEVENS, J., announced the judgment of the Court and delivered the opinion of the Court with respect to Parts I, II, III, V, and VII, in which KENNEDY, SOUTER, GINSBURG, and BREYER, JJ., joined, and an opinion with respect to Parts IV and VI, in which KENNEDY, SOUTER, and GINSBURG, JJ., joined. BREYER, J., filed an opinion concurring in part and concurring in the judgment, *post*, p. 503. O'CONNOR, J., filed an opinion concurring in part and dissenting in part, in which REHNQUIST, C. J., and SCALIA and THOMAS, JJ., joined, *post*, p. 509.

Arthur Miller argued the cause for Medtronic, Inc., in both cases. With him on the briefs were *Daniel G. Jarcho, Donald R. Stone, Kenneth S. Geller, Roy T. Englert, Jr., Alan E. Untereiner, Dennis P. Waggoner, Ronald E. Lund, John W. Borg,* and *Sue R. Halverson.*

Brian Wolfman argued the cause for Lohr et vir in both cases. With him on the brief were *Allison M. Zieve, Alan B. Morrison, Laurence H. Tribe, Robert L. Cowles,* and *Robert F. Spohrer.*

Deputy Solicitor General Kneedler argued the cause for the United States as *amicus curiae.* With him on the brief were *Solicitor General Days, Deputy Assistant Attorney General Preston, Richard H. Seamon,* and *Douglas N. Letter.*†

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†Briefs of *amici curiae* were filed for the State of California by *Daniel E. Lungren,* Attorney General, *Roderick E. Walston,* Chief Assistant Attorney General, *Theodora Berger,* Assistant Attorney General, and *Susan S. Fiering,* Deputy Attorney General; for the State of Florida et al. by *Robert A. Butterworth,* Attorney General of Florida, and *Louis F. Hubener* and *Charley McCoy,* Assistant Attorneys General, joined by the Attorneys General for their respective jurisdictions as follows: *Winston Bryant* of Arkansas, *Gale A. Norton* of Colorado, *Richard Blumenthal* of Connecticut, *Pamela Carter* of Indiana, *A. B. Chandler III* of Kentucky, *Andrew Ketterer* of Maine, *J. Joseph Curran, Jr.,* of Maryland, *Mike Moore* of Mississippi, *Jeremiah W. Nixon* of Missouri, *Joseph P. Mazurek* of Montana, *Tom Udall* of New Mexico, *Dennis C. Vacco* of New York, *Michael*

JUSTICE STEVENS announced the judgment of the Court and delivered the opinion of the Court with respect to Parts I, II, III, V, and VII, and an opinion with respect to Parts IV and VI, in which JUSTICE KENNEDY, JUSTICE SOUTER, and JUSTICE GINSBURG join.

Congress enacted the Medical Device Amendments of 1976, in the words of the statute's preamble, "to provide for the safety and effectiveness of medical devices intended for human use." 90 Stat. 539. The question presented is whether that statute pre-empts a state common-law negligence action against the manufacturer of an allegedly defective medical device. Specifically, we must consider whether Lora Lohr, who was injured when her pacemaker failed, may rely on Florida common law to recover damages from Medtronic, Inc., the manufacturer of the device.

F. Easley of North Carolina, *Heidi Heitkamp* of North Dakota, *Theodore R. Kulongoski* of Oregon, *Mark Barnett* of South Dakota, *Charles W. Burson* of Tennessee, *Dan Morales* of Texas, and *Darrell V. McGraw, Jr.*, of West Virginia; for the American Association of Retired Persons et al. by *David Halperin;* for the American Insurance Association et al. by *Victor E. Schwartz, Joseph N. Onek, Robert P. Charrow, Mark A. Behrens,* and *Jan S. Amundson;* for the Association of Trial Lawyers of America by *Jeffrey Robert White* and *Pamela A. Liapakis;* for the Center for Patient Advocacy et al. by *John G. Roberts, Jr.;* for Collagen Corp. by *Joe W. Redden, Jr., Keith A. Jones,* and *Frederick D. Baker;* for General Motors Corp. by *Kenneth W. Starr, Richard A. Cordray, Paul T. Cappuccio, David M. Heilbron, Leslie G. Landau,* and *James A. Durkin;* for the Health Industry Manufacturers Association et al. by *Bruce N. Kuhlik, Paul J. Maloney,* and *William J. Carter;* for the Medical Device Manufacturers Association by *Stephen S. Phillips* and *James M. Beck;* for the National Conference of State Legislatures et al. by *Richard Ruda* and *Lee Fennell;* for the Plaintiffs' Legal Committee in MDL Docket No. 1014 by *Stanley M. Chesley, John J. Cummings III, Calvin Fayard, Jr., Wendell Gauthier, Darryl J. Tschirn,* and *Michael D. Fishbein;* for the Product Liability Advisory Council, Inc., by *Robert N. Weiner* and *Hugh F. Young, Jr.;* for Trial Lawyers for Public Justice, P. C., by *Jonathan S. Massey* and *Arthur H. Bryant;* for the Washington Legal Foundation by *Daniel J. Popeo* and *Richard A. Samp;* and for Two Products Liability Law Professors by *Richard N. Pearson, pro se.*

I

Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens. Because these are "primarily, and historically, . . . matter[s] of local concern," *Hillsborough County* v. *Automated Medical Laboratories, Inc.*, 471 U. S. 707, 719 (1985), the "States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons," *Metropolitan Life Ins. Co.* v. *Massachusetts*, 471 U. S. 724, 756 (1985) (internal quotation marks omitted).

Despite the prominence of the States in matters of public health and safety, in recent decades the Federal Government has played an increasingly significant role in the protection of the health of our people. Congress' first significant enactment in the field of public health was the Food and Drug Act of 1906, a broad prohibition against the manufacture or shipment in interstate commerce of any adulterated or misbranded food or drug. See 34 Stat. 768; Regier, The Struggle for Federal Food and Drugs Legislation, 1 Law & Contemp. Prob. 1 (1933). Partly in response to an ongoing concern about radio and newspaper advertising making false therapeutic claims for both "quack machines" and legitimate devices such as surgical instruments and orthopedic shoes, in 1938 Congress broadened the coverage of the 1906 Act to include misbranded or adulterated medical devices and cosmetics. See Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), §§ 501, 502, 52 Stat. 1049–1051; Cavers, The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions, 6 Law & Contemp. Prob. 2 (1939); H. R. Rep. No. 94–853, p. 6 (1976).

While the FDCA provided for premarket approval of new drugs, Cavers, 6 Law & Contemp. Prob., at 40, it did not authorize any control over the introduction of new medical devices, see S. Rep. No. 93–670, pp. 1–2 (1974); H. R. Rep. No. 94–853, at 6. As technologies advanced and medicine

relied to an increasing degree on a vast array of medical equipment "[f]rom bedpans to brainscans,"[1] including kidney dialysis units, artificial heart valves, and heart pacemakers,[2] policymakers and the public became concerned about the increasingly severe injuries that resulted from the failure of such devices. See generally Finck, The Effectiveness of FDA Medical Device Regulation, 7 U. C. D. L. Rev. 293, 297–301 (1974); H. R. Rep. No. 94–853, at 7.

In 1970, for example, the Dalkon Shield, an intrauterine contraceptive device, was introduced to the American public and throughout the world. Touted as a safe and effective contraceptive, the Dalkon Shield resulted in a disturbingly high percentage of inadvertent pregnancies, serious infections, and even, in a few cases, death. *Id.*, at 8; Regulation of Medical Devices (Intrauterine Contraceptive Devices), Hearings before a Subcommittee of the House Committee on Government Operations, 93d Cong., 1st Sess. (1973). In the early 1970's, several other devices, including catheters, artificial heart valves, defibrillators, and pacemakers (including pacemakers manufactured by petitioner Medtronic), attracted the attention of consumers, the Food and Drug Administration (FDA), and Congress as possible health risks. See Medical Device Amendments, 1973, Hearings before the Subcommittee on Health of the Senate Committee on Labor and Public Welfare, 93d Cong., 2d Sess., 270–361 (1973).

In response to the mounting consumer and regulatory concern, Congress enacted the statute at issue here: the Medical Device Amendments of 1976 (MDA or Act), 90 Stat. 539. The Act classifies medical devices in three categories based on the risk that they pose to the public. Devices that pre-

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[1] Medical Device Regulation: The FDA's Neglected Child (Committee Print compiled for the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce), Comm. Print 98–F, p. 1 (1983).

[2] S. Rep. No. 94–33, p. 5 (1975).

sent no unreasonable risk of illness or injury are designated Class I and are subject only to minimal regulation by "general controls." 21 U. S. C. § 360c(a)(1)(A). Devices that are potentially more harmful are designated Class II; although they may be marketed without advance approval, manufacturers of such devices must comply with federal performance regulations known as "special controls." § 360c(a)(1)(B). Finally, devices that either "presen[t] a potential unreasonable risk of illness or injury," or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," are designated Class III. § 360c(a)(1)(C). Pacemakers are Class III devices. See 21 CFR § 870.3610 (1995).

Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. See 21 U. S. C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance," which is known as the "premarket approval," or "PMA" process, is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission. Hearings before the Subcommittee on Health and the Environment of the House Committee on Energy & Commerce, 100th Cong., 1st Sess. (Ser. No. 100–34), p. 384 (1987) (hereinafter 1987 Hearings); see generally Kahan, Premarket Approval Versus Premarket Notification: Different Routes to the Same Market, 39 Food Drug Cosm. L. J. 510, 512–514 (1984).

Not all, nor even most, Class III devices on the market today have received premarket approval because of two important exceptions to the PMA requirement. First, Congress realized that existing medical devices could not be

withdrawn from the market while the FDA completed its PMA analysis for those devices. The statute therefore includes a "grandfathering" provision which allows pre-1976 devices to remain on the market without FDA approval until such time as the FDA initiates and completes the requisite PMA. See 21 U. S. C. § 360e(b)(1)(A); 21 CFR § 814.1(c)(1) (1995).[3] Second, to prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market, the Act also permits devices that are "substantially equivalent" to pre-existing devices to avoid the PMA process. See 21 U. S. C. § 360e(b)(1)(B).

Although "substantially equivalent" Class III devices may be marketed without the rigorous PMA review, such new devices, as well as all new Class I and Class II devices, are subject to the requirements of § 360(k). That section imposes a limited form of review on every manufacturer intending to market a new device by requiring it to submit a "premarket notification" to the FDA (the process is also known as a "§ 510(k) process," after the number of the section in the original Act). If the FDA concludes on the basis of the § 510(k) notification that the device is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis (at least until the FDA initiates the PMA process for the underlying pre-1976 device to which the new device is "substantially equivalent"). The § 510(k) notification process is by no means comparable to the PMA

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[3] The FDA has not yet initiated nor suggested the initiation of a PMA process for pacemakers or most other grandfathered devices. But see 60 Fed. Reg. 41984, 41986 (1995) (pursuant to Safe Medical Devices Act of 1990, 104 Stat. 4511, calling for submission of information by February 1997 which may lead the FDA to reclassify or initiate PMA process at some time in the future for implantable pacemaker pulse generators and lead adapters).

process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours. See 1987 Hearings, at 384. As one commentator noted: "The attraction of substantial equivalence to manufacturers is clear. [Section] 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly." Adler, The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction, 43 Food Drug Cosm. L. J. 511, 516 (1988); see also Kahan, 39 Food Drug Cosm. L. J., at 514–519.

Congress anticipated that the FDA would complete the PMA process for Class III devices relatively swiftly. But because of the substantial investment of time and energy necessary for the resolution of each PMA application, the ever-increasing numbers of medical devices, and internal administrative and resource difficulties, the FDA simply could not keep up with the rigorous PMA process. As a result, the § 510(k) premarket notification process became the means by which most new medical devices—including Class III devices—were approved for the market. In 1983, for instance, a House Report concluded that nearly 1,000 of approximately 1,100 Class III devices that had been introduced to the market since 1976 were admitted as "substantial equivalents" and without any PMA review. See Medical Device Regulation: The FDA's Neglected Child (Committee Print compiled for the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce), Comm. Print 98–F, p. 34 (1983). This lopsidedness has apparently not evened out; despite an increasing effort by the FDA to consider the safety and efficacy of substantially equivalent devices, the House reported in 1990 that 80% of new Class III devices were being introduced to the market through the § 510(k) process and without PMA review. H. R. Rep. No. 101–808, p. 14 (1990); see also D. Kessler, S. Pape, &

D. Sundwall, The Federal Regulation of Medical Devices, 317 New England J. Med. 357, 359 (1987) (55 § 510(k) notifications are filed for each PMA application; average FDA response to § 510(k) notification is one-fifth the response time to a PMA).[4]

II

As have so many other medical device manufacturers, petitioner Medtronic took advantage of § 510(k)'s expedited process in October 1982, when it notified the FDA that it intended to market its Model 4011 pacemaker lead as a device that was "substantially equivalent" to devices already on the market. (The lead is the portion of a pacemaker that transmits the heartbeat-steadying electrical signal from the "pulse generator" to the heart itself.) On November 30, 1982, the FDA found that the model was "substantially equivalent to devices introduced into interstate commerce" prior to the effective date of the Act, and advised Medtronic that it could therefore market its device subject only to the general control provisions of the Act, which could be found in the Code of Federal Regulations. See Respondent's Memorandum in Support of Motion for Summary Judgment in No. 93–482 (MD Fla., Nov. 1, 1993), Exh. A to Exh. 1 (Declaration of Charles H. Swanson) (hereinafter FDA Substantial Equivalence Letter). The agency emphasized, however, that this determination should not be construed as an endorsement of the pacemaker lead's safety. *Ibid.*

Cross-petitioner Lora Lohr is dependent on pacemaker technology for the proper functioning of her heart. In 1987 she was implanted with a Medtronic pacemaker equipped with one of the company's Model 4011 pacemaker leads. On

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[4] In 1990, Congress enacted amendments to the MDA which were designed to reduce the FDA's reliance on the § 510(k) process while continuing to ensure that particularly risky devices received full PMA review. See Safe Medical Devices Act of 1990.

December 30, 1990, the pacemaker failed, allegedly resulting in a "complete heart block" that required emergency surgery. According to her physician, a defect in the lead was the likely cause of the failure.

In 1993 Lohr and her husband filed this action in a Florida state court. Their complaint contained both a negligence count and a strict-liability count. The negligence count alleged a breach of Medtronic's "duty to use reasonable care in the design, manufacture, assembly, and sale of the subject pacemaker" in several respects, including the use of defective materials in the lead and a failure to warn or properly instruct the plaintiff or her physicians of the tendency of the pacemaker to fail, despite knowledge of other earlier failures. Complaint ¶ 5. The strict-liability count alleged that the device was in a defective condition and unreasonably dangerous to foreseeable users at the time of its sale. *Id.*, ¶ 11. (A third count alleging breach of warranty was dismissed for failure to state a claim under Florida law.)

Medtronic removed the case to Federal District Court, where it filed a motion for summary judgment arguing that both the negligence and strict-liability claims were preempted by 21 U. S. C. § 360k(a). That section, which is at the core of the dispute between the parties in this suit, provides:

> "§ 360k. State and local requirements respecting devices
>
> "(a) General rule
>
> "Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> "(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

> "(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."[5]

The District Court initially denied Medtronic's motion, finding nothing in the statute to support the company's argument that the MDA entirely exempted from liability a manufacturer who had allegedly violated the FDA's regulations. See App. to Pet. for Cert. 5d. Not long after that decision, however, the United States Court of Appeals for the Eleventh Circuit concluded that § 360k required pre-emption of at least some common-law claims brought against the manu-

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[5] Subsection (b) of the statute authorizes the FDA to grant exemptions to state requirements that would otherwise be pre-empted by subsection (a). Section 360k(b) provides:

"(b) Exempt requirements

"Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

"(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

"(2) the requirement—

"(A) is required by compelling local conditions, and

"(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter."

To carry out this grant of authority, the FDA has issued regulations under the statute which both construe the scope of § 360k(a) and address the instances in which the FDA will grant exemptions to its pre-emptive effect. See 21 CFR § 808.1 (1995); n. 18, *infra*.

We note that although it is the FDA that exercises this authority, the Act gives that authority directly to the Secretary of Health and Human Services, who subsequently delegated her authority to the FDA. See, *e. g.*, 21 U. S. C. § 360k(b) ("the Secretary may" exempt state requirements), § 321(d) ("Secretary" defined as "the Secretary of Health and Human Services"). Under the FDCA, the Secretary is vested with "[t]he authority to promulgate regulations for the efficient enforcement of" the Act. 21 U. S. C. § 371(a).

facturer of a medical device. See *Duncan* v. *Iolab Corp.*, 12 F. 3d 194 (1994). After reconsidering its ruling in light of *Duncan*, the District Court reversed its earlier decision and dismissed the Lohrs' entire complaint.

The Court of Appeals reversed in part and affirmed in part. 56 F. 3d 1335 (CA11 1995). Rejecting the Lohrs' broadest submission, it first decided that "common law actions are state requirements within the meaning of § 360k(a)." *Id.*, at 1342. It next held that pre-emption could not be avoided by merely alleging that the negligence flowed from a violation of federal standards. *Id.*, at 1343. Then, after concluding that the term "requirements" in § 360k(a) was unclear, it sought guidance from FDA's regulations regarding pre-emption. Those regulations provide that a state requirement is not pre-empted unless the FDA has established " 'specific requirements applicable to a particular device.' " *Id.*, at 1344 (citing 21 CFR § 808.1(d) (1995)). Under these regulations, the court concluded, it was not necessary that the federal regulation specifically deal with pacemakers, but only that the federal requirement "should, in some way, be 'restricted by nature' to a particular process, procedure, or device and should not be completely open-ended," 56 F. 3d, at 1346 (footnote omitted), and that the specific device at issue should be subject to its requirements.

Under this approach, the court concluded that the Lohrs' negligent design claims were not pre-empted. It rejected Medtronic's argument that the FDA's finding of "substantial equivalence" had any significance with respect to the pacemaker's safety, or that the FDA's continued surveillance of the device constituted a federal "requirement" that its design be maintained. *Id.*, at 1347–1349. On the other hand, it concluded that the negligent manufacturing and failure to warn claims were pre-empted by FDA's general "good manufacturing practices" regulations, which establish general requirements for most steps in every device's manufacture, see *id.*, at 1350; 21 CFR §§ 820.20–820.198 (1995), and by the

FDA labeling regulations, which require devices to bear various warnings, see 56 F. 3d, at 1350–1351; 21 CFR § 801.109 (1995). The court made a parallel disposition of the strict-liability claims, holding that there was no pre-emption insofar as plaintiffs alleged an unreasonably dangerous design, but they could not revive the negligent manufacturing or failure to warn claims under a strict-liability theory. 56 F. 3d, at 1351–1352.

Medtronic filed a petition for certiorari seeking review of the Court of Appeals' decision insofar as it affirmed the District Court and the Lohrs filed a cross-petition seeking review of the judgment insofar as it upheld the pre-emption defense. Because the Courts of Appeals are divided over the extent to which state common-law claims are pre-empted by the MDA,[6] we granted both petitions. 516 U. S. 1087 (1996).

III

As in *Cipollone* v. *Liggett Group, Inc.*, 505 U. S. 504 (1992), we are presented with the task of interpreting a statutory provision that expressly pre-empts state law. While the pre-emptive language of § 360k(a) means that we need not go beyond that language to determine whether Congress intended the MDA to pre-empt at least some state law, see *id.*, at 517, we must nonetheless "identify the domain expressly pre-empted" by that language, *ibid.* Although our analysis of the scope of the pre-emption statute must begin with its text, see *Gade* v. *National Solid Wastes Management Assn.*,

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[6] See, *e. g.*, *English* v. *Mentor Corp.*, 67 F. 3d 477 (CA3 1995) (§ 510(k) process creates pre-emptive "requirements"); *Feldt* v. *Mentor Corp.*, 61 F. 3d 431 (CA5 1995) (§ 510(k) process does not create pre-emptive "requirements"); *Michael* v. *Shiley, Inc.*, 46 F. 3d 1316 (CA3 1995) (claim alleging violation of federal requirement not pre-empted); 56 F. 3d 1335 (CA11 1995) (case below) (claim alleging violation of federal requirement may be pre-empted; § 510(k) process may create pre-emptive requirements; common-law claims covered by § 360k(a)); *Kennedy* v. *Collagen Corp.*, 67 F. 3d 1453 (CA9 1995) (common-law claims not covered at all by § 360k(a)).

505 U. S. 88, 111 (1992) (KENNEDY, J., concurring in part and concurring in judgment), our interpretation of that language does not occur in a contextual vacuum. Rather, that interpretation is informed by two presumptions about the nature of pre-emption. See *ibid.*

First, because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has "legislated . . . in a field which the States have traditionally occupied," *Rice* v. *Santa Fe Elevator Corp.*, 331 U. S. 218, 230 (1947), we "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Ibid.; Hillsborough Cty.*, 471 U. S., at 715–716; cf. *Fort Halifax Packing Co.* v. *Coyne*, 482 U. S. 1, 22 (1987). Although dissenting Justices have argued that this assumption should apply only to the question whether Congress intended any pre-emption at all, as opposed to questions concerning the *scope* of its intended invalidation of state law, see *Cipollone*, 505 U. S., at 545–546 (SCALIA, J., concurring in judgment in part and dissenting in part), we used a "presumption against the pre-emption of state police power regulations" to support a narrow interpretation of such an express command in *Cipollone*. *Id.*, at 518, 523. That approach is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety.

Second, our analysis of the scope of the statute's pre-emption is guided by our oft-repeated comment, initially made in *Retail Clerks* v. *Schermerhorn*, 375 U. S. 96, 103 (1963), that "[t]he purpose of Congress is the ultimate touchstone" in every pre-emption case. See, *e. g.*, *Cipollone*, 505 U. S., at 516; *Gade*, 505 U. S., at 96; *Malone* v. *White Motor Corp.*, 435 U. S. 497, 504 (1978). As a result, any understanding of the scope of a pre-emption statute must rest pri-

marily on "a fair understanding of *congressional purpose.*" *Cipollone*, 505 U. S., at 530, n. 27 (opinion of STEVENS, J.). Congress' intent, of course, primarily is discerned from the language of the pre-emption statute and the "statutory framework" surrounding it. *Gade*, 505 U. S., at 111 (KENNEDY, J., concurring in part and concurring in judgment). Also relevant, however, is the "structure and purpose of the statute as a whole," *id.*, at 98 (opinion of O'CONNOR, J.), as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law.

With these considerations in mind, we turn first to a consideration of petitioner Medtronic's claim that the Court of Appeals should have found the entire action pre-empted and then to the merits of the Lohrs' cross-petition.

IV

In its petition, Medtronic argues that the Court of Appeals erred by concluding that the Lohrs' claims alleging negligent design were not pre-empted by 21 U. S. C. § 360k(a). That section provides that "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." Medtronic suggests that any common-law cause of action is a "requirement" which alters incentives and imposes duties "different from, or in addition to," the generic federal standards that the FDA has promulgated in response to mandates under the MDA. In essence, the company argues that the plain language of the statute pre-empts any and all common-law claims brought by an injured plaintiff against a manufacturer of medical devices.

Medtronic's argument is not only unpersuasive, it is implausible. Under Medtronic's view of the statute, Congress effectively precluded state courts from affording state consumers any protection from injuries resulting from a defective medical device. Moreover, because there is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action, Congress would have barred most, if not all, relief for persons injured by defective medical devices.[7] Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order "to provide for the safety and effectiveness of medical devices intended for human use," 90 Stat. 539 (preamble to Act). It is, to say the least, "difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct," *Silkwood* v. *Kerr-McGee Corp.*, 464 U. S. 238, 251 (1984), and it would take language much plainer than the text of § 360k to convince us that Congress intended that result.

Furthermore, if Congress intended to preclude all common-law causes of action, it chose a singularly odd word with which to do it. The statute would have achieved an identical result, for instance, if it had precluded any "remedy" under state law relating to medical devices. "Requirement" appears to presume that the State is imposing a specific duty upon the manufacturer, and although we have on prior occasions concluded that a statute pre-empting certain

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[7] The FDA's authority to require manufacturers to recall, replace, or refund defective devices is of little use to injured plaintiffs, since there is no indication that the right is available to private parties, the remedy would not extend to recovery for compensatory damages, and the authority is rarely invoked, if at all. See Adler, The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction, 43 Food Drug Cosm. L. J. 511, 526–527 (1988).

state "requirements" could also pre-empt common-law damages claims, see *Cipollone*, 505 U. S., at 521–522 (opinion of STEVENS, J.), that statute did not sweep nearly as broadly as Medtronic would have us believe that this statute does.

The pre-emptive statute in *Cipollone*[8] was targeted at a limited set of state requirements—those "based on smoking and health"—and then only at a limited subset of the possible applications of those requirements—those involving the "advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of" the federal statute. See *id.*, at 515. In that context, giving the term "requirement" its widest reasonable meaning did not have nearly the pre-emptive scope nor the effect on potential remedies that Medtronic's broad reading of the term would have in this suit. The Court in *Cipollone* held that the petitioner in that case was able to maintain some common-law actions using theories of the case that did not run afoul of the pre-emption statute. See *id.*, at 524–530. Here, however, Medtronic's sweeping interpretation of the statute would require far greater interference with state legal remedies, producing a serious intrusion into state sovereignty while simultaneously wiping out the possibility of remedy for the

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[8] There were actually two pre-emptive statutes at issue: The first, enacted in 1965, provided that "[n]o statement relating to smoking and health . . . shall be required" on any cigarette package or in any cigarette advertising. See *Cipollone* v. *Liggett Group, Inc.*, 505 U. S., at 514. That provision, the Court concluded, did not pre-empt any of the petitioner's common-law claims. *Id.*, at 518–520. In 1969, Congress superseded the 1965 pre-emption statute with part of the Public Health Cigarette Smoking Act of 1969, which provided that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." *Id.*, at 515. The bulk of *Cipollone*'s analysis involved this later statute; unless otherwise stated, it is this statute to which we refer in subsequent references to the pre-emptive statute in *Cipollone*.

Lohrs' alleged injuries.[9] Given the ambiguities in the statute and the scope of the preclusion that would occur otherwise, we cannot accept Medtronic's argument that by using the term "requirement," Congress clearly signaled its intent to deprive States of any role in protecting consumers from the dangers inherent in many medical devices.

Other differences between this statute and the one in *Cipollone* further convince us that when Congress enacted § 360k, it was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions. Unlike the statute at issue in *Cipollone,* § 360k refers to "requirements" many times throughout its text. In each instance, the word is linked with language suggesting that its focus is device-specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries. For instance, subsections (a)(2) and (b) of the statute[10] also refer to "requirements"—but those "requirements" refer only to statutory and regulatory law that exists pursuant to the MDA itself, suggesting that the pre-empted "requirements" established or continued by States also refer primarily to positive enactments of state law. Moreover, in subsection (b) the FDA is given authority to exclude certain "requirements" from the scope of the pre-emption statute. Of the limited number of "exemptions"

[9] Unlike § 360k, the pre-emptive effect of the statute in *Cipollone* was not dependent on the issuance of any agency regulations. The territory exclusively occupied by federal law was defined in the text of the statute itself; that text specified the precise warning to smokers that Congress deemed both necessary and sufficient. In the MDA, no such specifics exist until the FDA provides them. See also *infra,* at 495–496 (reliance on the FDA's interpretation of § 360k warranted, *inter alia,* because of the FDA's role in the administration of § 360k). Moreover, the statute in *Cipollone* was clearly intended to have a broader pre-emptive effect than its 1965 predecessor. See 505 U. S., at 515, 520–521.

[10] The text of the statute is quoted *supra,* at 482, and n. 5.

from pre-emption that the FDA has granted, none even remotely resemble common-law claims.[11]

An examination of the basic purpose of the legislation as well as its history entirely supports our rejection of Medtronic's extreme position. The MDA was enacted "to provide for the safety and effectiveness of medical devices intended for human use." 90 Stat. 539. Medtronic asserts that the Act was also intended, however, to "protect innovations in device technology from being 'stifled by unnecessary restrictions,'" Brief for Petitioner in No. 95–754, p. 3 (citing H. R. Rep. No. 94–853, at 12), and that this interest extended to the pre-emption of common-law claims. While the Act certainly reflects some of these concerns,[12] the legislative history indicates that any fears regarding regulatory burdens were related more to the risk of *additional* federal and state regulation rather than the danger of pre-existing duties under common law. See, *e. g.*, 122 Cong. Rec. 5850 (1976) (statement of Rep. Collins) (opposing further "redundant and burdensome Federal requirements"); *id.*, at 5855 (discussing efforts taken in MDA to protect small businesses from the additional requirements of the Act). Indeed, nowhere in the materials relating to the Act's history have we discovered a reference to a fear that product liability actions would hamper the development of medical devices. To the extent that Congress was concerned about protecting the industry, that intent was manifested primarily through fewer substantive requirements under the Act, not the pre-emption provision; furthermore, any such concern was far outweighed by con-

[11] All 22 exemptions at 21 CFR §§ 808.53–808.101 (1995) are exemptions for state statutes and regulations regarding the sale of hearing aids.

[12] Special statutory exemptions, for example, permit the FDA (with various oversight provisions) to allow investigative, experimental devices to be used in commerce without either PMA review or "substantial equivalence." See 21 U. S. C. § 360j(g); 21 CFR pt. 813 (1995). Moreover, the very existence of the pre-emption statute demonstrates some concern that competing state requirements may unduly interfere with the market for medical devices.

cerns about the primary issue motivating the MDA's enactment: the safety of those who use medical devices.

The legislative history also confirms our understanding that § 360(k) simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions. There is, to the best of our knowledge, nothing in the hearings, the Committee Reports, or the debates suggesting that any proponent of the legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices. If Congress intended such a result, its failure even to hint at it is spectacularly odd, particularly since Members of both Houses were acutely aware of ongoing product liability litigation.[13] Along with the less-than-precise language of § 360k(a), that silence surely indicates that at least some common-law claims against medical device manufacturers may be maintained after the enactment of the MDA.

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[13] Furthermore, if Congress had intended the MDA to work this dramatic change in the availability of state-law remedies, one would expect some reference to that change in the extensive contemporary reviews of the legislation. We have been able to find no such reference. See, *e. g.*, Lesparre, Industry Spokesman Comments on Medical Device Amendments of 1976, 50 Hospitals 99, 103 (Sept. 16, 1976); A. Levine, Device Failure and the Plaintiff's Lawyer, in Proceedings of the Second Annual AAMI/FDA Conference on Medical Device Regulation 54 (1975); Medical Device Amendments of 1975, Hearings before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce, Ser. No. 94–39, 94th Cong., 1st Sess., 271 (1975) (statement of Anita Johnson, Public Citizen's Health Research Group) (arguing that the pre-emption provision should not be included, but making no mention of common law, and specifically discussing only a positive California enactment regarding the safety of intrauterine contraceptive devices); Medical Devices and Equipment Liability Avoidance (Frost & Sullivan pub. June 1977) (comprehensive 2-volume, 600-page review of published medical device product liability cases from 1910 to 1976, suggesting nowhere that MDA had mooted or even altered the longstanding ability of plaintiffs to seek and receive damages awards under state law).

V

Medtronic asserts several specific reasons why, even if § 360k does not pre-empt all common-law claims, it at least pre-empts the Lohrs' claims in this suit. In contrast, the Lohrs argue that their entire complaint should survive a reasonable evaluation of the pre-emptive scope of § 360k(a). First, the Lohrs claim that the Court of Appeals correctly held that their negligent design claims were not pre-empted because the § 510(k) premarket notification process imposes no "requirement" on the design of Medtronic's pacemaker. Second, they suggest that even if the FDA's general rules regulating manufacturing practices and labeling are "requirements" that pre-empt *different* state requirements, § 360k(a) does not pre-empt state rules that merely duplicate some or all of those federal requirements. Finally, they argue that because the State's general rules imposing common-law duties upon Medtronic do not impose a requirement "with respect to a device," they do not conflict with the FDA's general rules relating to manufacturing and labeling and are therefore not pre-empted.

Design Claim

The Court of Appeals concluded that the Lohrs' defective design claims were not pre-empted because the requirements with which the company had to comply were not sufficiently concrete to constitute a pre-empting federal requirement. Medtronic counters by pointing to the FDA's determination that Model 4011 is "substantially equivalent" to an earlier device as well as the agency's continuing authority to exclude the device from the market if its design is changed. These factors, Medtronic argues, amount to a specific, federally enforceable design requirement that cannot be affected by state-law pressures such as those imposed on manufacturers subject to product liability suits.

The company's defense exaggerates the importance of the § 510(k) process and the FDA letter to the company regard-

ing the pacemaker's substantial equivalence to a grandfathered device. As the court below noted, "[t]he 510(k) process is focused on *equivalence*, not safety." 56 F. 3d, at 1348. As a result, "substantial equivalence determinations provide little protection to the public. These determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective." Adler, 43 Food Drug Cosm. L. J., at 516. The design of the Model 4011, as with the design of pre-1976 and other "substantially equivalent" devices, has never been formally reviewed under the MDA for safety or efficacy.

The FDA stressed this basic conclusion in its letter to Medtronic finding the 4011 lead "substantially equivalent" to devices already on the market. That letter only required Medtronic to comply with "general standards"—the lowest level of protection "applicable to all medical devices," and including "listing of devices, good manufacturing practices, labeling, and the misbranding and adulteration provisions of the Act." It explicitly warned Medtronic that the letter did "not in any way denote official FDA approval of your device," and that "[a]ny representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding." FDA Substantial Equivalence Letter.

Thus, even though the FDA may well examine § 510(k) applications for Class III devices (as it examines the entire medical device industry) with a concern for the safety and effectiveness of the device, see Brief for Petitioner in No. 95–754, at 22–26, it did not "require" Medtronics' pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before 1976, to be

marketed without running the gauntlet of the PMA process. In providing for this exemption to PMA review, Congress intended merely to give manufacturers the freedom to compete, to a limited degree, with and on the same terms as manufacturers of medical devices that existed prior to 1976.[14] There is no suggestion in either the statutory scheme or the legislative history that the § 510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents. That status quo included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design. Given this background behind the "substantial equivalence" exemption, the fact that "[t]he purpose of Congress is the ultimate touchstone" in every pre-emption case, 505 U. S., at 516 (internal quotation marks and citations omitted), and the presumption against pre-emption, the Court of Appeals properly concluded that the "substantial equivalence" provision did not pre-empt the Lohrs' design claims.

Identity of Requirements Claims

The Lohrs next suggest that even if "requirements" exist with respect to the manufacturing and labeling of the pace-

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[14] As the FDA Commissioner put it in 1982: "[T]he 510(k) provision of the law is a procompetition mechanism that permits firms to make and quickly market me-too versions of pre-1976 devices. The Congress apparently believed that a firm whose device happened to be on the market before enactment of the amendments and was never subject to preclearance by FDA should not enjoy a lengthy monopoly at the expense of other firms and ultimately the consumer." FDA Oversight: Medical Devices, Hearing before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, 97th Cong., 2d Sess., 9 (1982). See also Kahan, Premarket Approval Versus Premarket Notification: Different Routes to the Same Market, 39 Food Drug Cosm. L. J. 510, 514–515 (1984); D. Kessler, S. Pape, & D. Sundwall, The Federal Regulation of Medical Devices, 317 New England J. Med. 357, 359 (1987).

maker, and even if we can also consider state law to impose a "requirement" under the Act, the state requirement is not pre-empted unless it is "different from, or in addition to," the federal requirement. § 360k(a)(1). Although the precise contours of their theory of recovery have not yet been defined (the pre-emption issue was decided on the basis of the pleadings), it is clear that the Lohrs' allegations may include claims that Medtronic has, to the extent that they exist, violated FDA regulations. At least these claims, they suggest, can be maintained without being pre-empted by § 360k, and we agree.

Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

The FDA regulations interpreting the scope of § 360k's pre-emptive effect support the Lohrs' view, and our interpretation of the pre-emption statute is substantially informed by those regulations. The different views expressed by the Courts of Appeals regarding the appropriate scope of federal pre-emption under § 360k demonstrate that the language of that section is not entirely clear. In addition, Congress has

given the FDA a unique role in determining the scope of § 360k's pre-emptive effect. Unlike the statute construed in *Cipollone*, for instance, pre-emption under the MDA does not arise directly as a result of the enactment of the statute; rather, in most cases a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal "requirement." Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act,[15] the agency is uniquely qualified to determine whether a particular form of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines* v. *Davidowitz*, 312 U. S. 52, 67 (1941), and, therefore, whether it should be pre-empted. For example, Congress explicitly delegated to the FDA the authority to exempt state regulations from the pre-emptive effect of the MDA—an authority that necessarily requires the FDA to assess the pre-emptive effect that the Act and its own regulations will have on state laws. See § 360k(b). FDA regulations implementing that grant of authority establish a process by which States or other individuals may request an advisory opinion from the FDA regarding whether a particular state requirement is pre-empted by the statute. See 21 CFR § 808.5 (1995). The ambiguity in the statute—and the congressional grant of authority to the agency on the matter contained within it—provide a "sound basis," *post*, at 509 (O'CONNOR, J., concurring in part and dissenting in part), for giving substantial weight to the agency's view of the statute. See *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837 (1984); *Hillsborough Cty.*, 471 U. S., at 714 (considering FDA understanding of pre-emptive effect of its regulations "dispositive").

The regulations promulgated by the FDA expressly support the conclusion that § 360k "does not preempt State or local requirements that are equal to, or substantially identi-

[15] See n. 5, *supra*; 21 U. S. C. § 371(a).

cal to, requirements imposed by or under the act." 21 CFR §808.1(d)(2) (1995); see also §808.5(b)(1)(i).[16] At this early stage in the litigation, there was no reason for the Court of Appeals to preclude altogether the Lohrs' manufacturing and labeling claims to the extent that they rest on claims that Medtronic negligently failed to comply with duties "equal to, or substantially identical to, requirements imposed" under federal law.

Manufacturing and Labeling Claims

Finally, the Lohrs suggest that with respect to the manufacturing and labeling claims, the Court of Appeals should have rejected Medtronic's pre-emption defense in full. The Court of Appeals believed that these claims would interfere with the consistent application of general federal regulations governing the labeling and manufacture of all medical devices, and therefore concluded that the claims were pre-empted altogether.

The requirements identified by the Court of Appeals include labeling regulations that require manufacturers of every medical device, with a few limited exceptions, to include with the device a label containing "information for use, . . . and any relevant hazards, contraindications, side effects, and precautions." 21 CFR §§801.109(b) and (c) (1995). Similarly, manufacturers are required to comply with "Good Manufacturing Practices," or "GMP's," which are set forth in 32 sections and less than 10 pages in the Code of Federal Regulations.[17] In certain circumstances, the Court of Ap-

[16] We also note that the agency permits manufacturers of devices that have received PMA to make certain labeling, quality control, and manufacturing changes which would "enhanc[e] the safety of the device or the safety in the use of the device" without prior FDA approval. See 21 CFR §§814.39(d)(1) and (2) (1995).

[17] Some GMP's include the duty to institute a "quality assurance program," §820.5, to have an "adequate organizational structure," §820.20, to ensure that personnel in contact with a device are "clean, healthy, and suitably attired" where such matters are relevant to the device's safety,

peals recognized, the FDA will enforce these general requirements against manufacturers that violate them. See 56 F. 3d, at 1350–1351.

While admitting that these requirements exist, the Lohrs suggest that their general nature simply does not pre-empt claims alleging that the manufacturer failed to comply with other duties under state common law. In support of their claim, they note that § 360k(a)(1) expressly states that a federal requirement must be "applicable to the device" in question before it has any pre-emptive effect. Because the labeling and manufacturing requirements are applicable to a host of different devices, they argue that they do not satisfy this condition. They further argue that because only state requirements "with respect to a device" may be pre-empted, and then only if the requirement "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device," § 360k(a) mandates pre-emption only where there is a conflict between a specific state requirement and a federal requirement "applicable to" the same device.

The Lohrs' theory is supported by the FDA regulations, which provide that state requirements are pre-empted "only" when the FDA has established "specific counterpart regulations or . . . other specific requirements applicable to a particular device." 21 CFR § 808.1(d) (1995).[18] They fur-

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§ 820.25, and to have buildings, environmental controls, and equipment of a quality adequate to produce a safe product, see §§ 820.40, 820.46, 820.60.

[18] FDA's narrow understanding of the scope of § 360k(a) is obvious from the full text of the regulation, which provides, in relevant part:

"(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by

ther note that the statute is not intended to pre-empt "State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices." § 808.1(d)(1). The regulations specifically provide, as examples of permissible general requirements, that general electrical codes and the Uniform Commercial Code warranty of fitness would not be pre-empted. See *ibid.* The regulations even go so far as to state that § 360k(a) generally "does not preempt a state or local requirement prohibiting the manufacture of adulterated or misbranded devices" unless "such a prohibition has the effect of establishing a substantive requirement for a specific device." § 808.1(d)(6)(ii). Furthermore, under its authority to grant exemptions to the pre-emptive effect of § 360k(a), the FDA has never granted, nor, to the best of our

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section 521(a) of the act because they are not 'requirements applicable to a device' within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

"(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e. g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

"(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

. . . . .

"(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e. g., requirements that State inspection be permitted of factory records concerning all devices. . . .

"(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e. g., a specific labeling requirement, then the prohibition [may] be preempted." 21 CFR § 808.1(d) (1995).

knowledge, even been asked to consider granting, an exemption for a state law of general applicability; all 22 existing exemptions apply to excruciatingly specific state requirements regarding the sale of hearing aids. See §§ 808.53–808.101.

Although we do not believe that this statutory and regulatory language necessarily precludes "general" federal requirements from ever pre-empting state requirements, or "general" state requirements from ever being pre-empted, see Part VI, *infra*, it is impossible to ignore its overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest. State requirements must be "with respect to" medical devices and "different from, or in addition to," federal requirements. State requirements must also relate "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device," and the regulations provide that state requirements of "general applicability" are not pre-empted except where they have "the effect of establishing a substantive requirement for a specific device." Moreover, federal requirements must be "applicable to the device" in question, and, according to the regulations, pre-empt state law only if they are "specific counterpart regulations" or "specific" to a "particular device." The statute and regulations, therefore, require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations.[19]

[19] A plurality of this Court concluded in *Cipollone* that a similar analysis was required under the Public Health Cigarette Smoking Act of 1969. That Act pre-empted requirements and prohibitions based on smoking and health "imposed under State law with respect to the advertising or promotion" of cigarettes in packages that were labeled in conformity with that Act. 505 U. S., at 515. We held that the petitioner's fraudulent misrepresentation claims, including those based on allegedly false statements made in advertisements, were not pre-empted because they were "predicated not on a duty 'based on smoking and health' but rather on a more general

Such a comparison mandates a conclusion that the Lohrs' common-law claims are not pre-empted by the federal labeling and manufacturing requirements. The generality of those requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. Rather, the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements.

Similarly, the general state common-law requirements in this suit were not specifically developed "with respect to" medical devices. Accordingly, they are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements. The legal duty that is the predicate for the Lohrs' negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regula-

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obligation—the duty not to deceive." *Id.*, at 528–529. The general common-law duty "not to make fraudulent statements" was not within the specific category of requirements or prohibitions based on smoking and health imposed under state law "with respect to the advertising or promotion" of cigarettes that were pre-empted by the 1969 statute. *Id.*, at 529.

If anything, the language of the MDA's pre-emption statute and its counterpart regulations require an even more searching inquiry into the relationship between the federal requirement and the state requirement at issue than was true under the statute in *Cipollone*.

tions and zoning codes, or to use due care in the training and supervision of a work force. These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be "with respect to" specific devices such as pacemakers. As a result, none of the Lohrs' claims based on allegedly defective manufacturing or labeling are pre-empted by the MDA.

VI

In their cross-petition, the Lohrs present a final argument, suggesting that common-law duties are never "requirements" within the meaning of § 360k and that the statute therefore never pre-empts common-law actions. The Lohrs point out that our holding in *Cipollone* is not dispositive of this issue, for as Part IV, *supra*, suggests, there are significant textual and historical differences between the *Cipollone* statute and § 360k, and the meaning of words must always be informed by the environment within which they are situated. We do not think that the issue is resolved by the FDA regulation suggesting that § 360k is applicable to those requirements "having the force and effect of law" that are "established by . . . court decision," 21 CFR § 808.1(b) (1995); that reference, it appears, was intended to refer to court decisions *construing* state statutes or regulations. See 42 Fed. Reg. 30383, 30385 (1977); Brief for Petitioners in No. 95–886, p. 26, n. 7.

Nevertheless, we do not respond directly to this argument for two reasons. First, since none of the Lohrs' claims is pre-empted in this suit, we need not resolve hypothetical cases that may arise in the future. Second, given the critical importance of device specificity in our (and the FDA's) construction of § 360k, it is apparent that few, if any, common-law duties have been pre-empted by this statute. It will be rare indeed for a court hearing a common-law

cause of action to issue a decree that has "the effect of establishing a substantive requirement for a specific device." 21 CFR § 808.1(d)(6)(ii) (1995). Until such a case arises, we see no need to determine whether the statute explicitly pre-empts such a claim. Even then, the issue may not need to be resolved if the claim would also be pre-empted under conflict pre-emption analysis, see *Freightliner Corp.* v. *Myrick*, 514 U. S. 280, 287 (1995).

VII

Accordingly, the judgment of the Court of Appeals is reversed insofar as it held that any of the claims were pre-empted and affirmed insofar as it rejected the pre-emption defense. The cases are remanded for further proceedings.

It is so ordered.

JUSTICE BREYER, concurring in part and concurring in the judgment.

This action raises two questions. First, do the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act ever pre-empt a state-law tort action? Second, if so, does the MDA pre-empt the particular state-law tort claims at issue here?

I

My answer to the first question is that the MDA will sometimes pre-empt a state-law tort suit. I basically agree with JUSTICE O'CONNOR's discussion of this point and with her conclusion. See *post*, at 510–512. The statute's language, read literally, supports that conclusion. It says:

> "[N]o State . . . may establish . . . with respect to a device . . . any [state] *requirement* . . . which is different from, or in addition to, any [federal] requirement . . . ." 21 U. S. C. § 360k(a) (emphasis added).

One can reasonably read the word "requirement" as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law.

Moreover, in *Cipollone* v. *Liggett Group, Inc.*, 505 U. S. 504 (1992), the Court made clear that similar language "easily" encompassed tort actions because "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief." *Id.*, at 521 (plurality opinion) (internal quotation marks omitted); see *id.*, at 548–549 (SCALIA, J., concurring in judgment in part and dissenting in part). Accord, *CSX Transp., Inc.* v. *Easterwood*, 507 U. S. 658, 664 (1993). This rationale would seem applicable to the quite similar circumstances at issue here.

Finally, a contrary holding would have anomalous consequences. Imagine that, in respect to a particular hearing aid component, a federal MDA regulation requires a 2-inch wire, but a state agency regulation requires a 1-inch wire. If the federal law, embodied in the "2-inch" MDA regulation, pre-empts the state "1-inch" agency regulation, why would it not similarly pre-empt a state-law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury persuaded by expert testimony that use of a more than 1-inch wire is negligent)? The effects of the state agency regulation and the state tort suit are identical. To distinguish between them for pre-emption purposes would grant greater power (to set state standards "different from, or in addition to," federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes. Where Congress likely did not focus specifically upon the matter, see *ante*, at 486–491, I would not take it to have intended this anomalous result.

Consequently, I believe that ordinarily, insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a

standard of care or behavior imposed by a state-law tort action. It is possible that the plurality also agrees on this point, although it does not say so explicitly.

II

The answer to the second question turns on Congress' intent. See, *e. g., Barnett Bank of Marion Cty., N. A.* v. *Nelson*, 517 U. S. 25, 30 (1996); *Allis-Chalmers Corp.* v. *Lueck*, 471 U. S. 202, 208 (1985); *ante*, at 485–486. Although Congress has not stated whether the MDA does, or does not, pre-empt the tort claims here at issue, several considerations lead me to conclude that it does not.

First, the MDA's pre-emption provision is highly ambiguous. That provision makes clear that federal requirements may pre-empt state requirements, but it says next to nothing about just when, where, or how they may do so. The words "any [state] requirement" and "any [federal] requirement," for example, do not tell us *which* requirements are at issue, for *every* state requirement that is not identical to even *one* federal requirement is "different from, or in addition to," that single federal requirement; yet, Congress could not have intended that the existence of one single federal rule, say, about a 2-inch hearing aid wire, would pre-empt *every* state law hearing aid rule, even a set of rules related only to the packaging or shipping of hearing aids. Thus, Congress must have intended that courts look elsewhere for help as to just which federal requirements pre-empt just which state requirements, as well as just how they might do so.

Second, this Court has previously suggested that, in the absence of a clear congressional command as to pre-emption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect. See *Hillsborough County* v. *Automated Medical Laboratories, Inc.*, 471 U. S. 707, 721 (1985); cf. *Smiley* v. *Citibank (South Dakota), N. A.*, 517 U. S. 735, 739–741

(1996); *Lawrence County* v. *Lead-Deadwood School Dist. No. 40–1*, 469 U. S. 256, 261–262 (1985); *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U. S. 837, 842–845 (1984). To draw a similar inference here makes sense, and not simply because of the statutory ambiguity. The Food and Drug Administration (FDA) is fully responsible for administering the MDA. See 21 U. S. C. §393. That responsibility means informed agency involvement and, therefore, special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether (or the extent to which) state requirements may interfere with federal objectives. See *Hillsborough*, 471 U. S., at 721. The FDA can translate these understandings into particularized pre-emptive intentions accompanying its various rules and regulations. See *id.*, at 718. It can communicate those intentions, for example, through statements in "regulations, preambles, interpretive statements, and responses to comments," *ibid.*, as well as through the exercise of its explicitly designated power to exempt state requirements from pre-emption, see 21 U. S. C. §360k(b); see also *ante*, at 496 (noting that FDA's authority to exempt state requirements from pre-emption necessarily requires FDA to assess federal laws' pre-emptive effect).

Third, the FDA has promulgated a specific regulation designed to help. That regulation says:

> "State . . . requirements are preempted only when . . . there are . . . *specific* [federal] requirements applicable to a particular device . . . thereby making any existing *divergent* State . . . requirements applicable to the device different from, or in addition to, the *specific* [federal] requirements." 21 CFR §808.1(d) (1995) (emphasis added).

The regulation does not fill all the statutory gaps, for its word "divergent" does not explain, any more than did the statute, just when different device-related federal and state

requirements are closely enough related to trigger pre-emption analysis. But the regulation's word "specific" does narrow the universe of federal requirements that the agency intends to displace at least some state law.

Insofar as there are any applicable FDA requirements here, those requirements, even if numerous, are not "specific" in any relevant sense. See *ante*, at 497–498, 501. Hence, as the FDA's above-quoted pre-emption rule tells us, the FDA does not intend these requirements to pre-empt the state requirements at issue here. At least in present circumstances, no law forces the FDA to make its requirements pre-emptive if it does not think it appropriate.

I cannot infer a contrary intent from JUSTICE O'CONNOR's characterization of the federal standards applicable here as "comprehensive" and "extensive," *post*, at 513, 514, both because that characterization is questionable, see *ante*, at 497–498, 501, and because this Court has previously said that it would "seldom infer, solely from the comprehensiveness of federal regulations, an intent to pre-empt in its entirety a field related to health and safety." *Hillsborough*, *supra*, at 718. It therefore seems to me that the better indicator of the FDA's intent is its pre-emption-related regulation. And that regulation's word "specific" would seem a reasonable exercise of the leeway that statutory language and practical administrative circumstance suggest Congress intended to grant to the agency.

Fourth, ordinary principles of "conflict" and "field" pre-emption point in the same direction. Those principles make clear that a federal requirement pre-empts a state requirement if (1) the state requirement actually conflicts with the federal requirement—either because compliance with both is impossible, *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U. S. 132, 142–143 (1963), or because the state requirement "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines* v. *Davidowitz*, 312 U. S. 52, 67 (1941)—or (2) the

scheme of federal regulation is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," *Rice* v. *Santa Fe Elevator Corp.*, 331 U. S. 218, 230 (1947). See, *e. g.*, *Barnett Bank*, 517 U. S., at 31; *Gade* v. *National Solid Wastes Management Assn.*, 505 U. S. 88, 98 (1992) (opinion of O'CONNOR, J.); *Wisconsin Public Intervenor* v. *Mortier*, 501 U. S. 597, 604–605 (1991); *English* v. *General Elec. Co.*, 496 U. S. 72, 79 (1990).

It makes sense, in the absence of any indication of a contrary congressional (or agency) intent, to read the pre-emption statute (and the pre-emption regulation) in light of these basic pre-emption principles. The statutory terms "different from" and "in addition to" readily lend themselves to such a reading, for their language parallels pre-emption law's basic concerns. Without any contrary indication from the agency, one might also interpret the regulation's word "divergent" in light of these same basic pre-emption principles.

Insofar as these basic principles inform a court's interpretation of the statute and regulation, they support the conclusion that there is no pre-emption here. I can find no actual conflict between any federal requirement and any of the liability-creating premises of the plaintiffs' state-law tort suit; nor, for the reasons discussed above, can I find any indication that either Congress or the FDA intended the relevant FDA regulations to occupy entirely any relevant field.

For these reasons, I concur in the Court's judgment. I also join the Court's opinion, but for Parts IV and VI. I do not join Part IV, which emphasizes the differences between the MDA and the pre-emption statute at issue in *Cipollone*, because those differences are not, in my view, relevant in this action. I do not join Part VI, because I am not convinced that future incidents of MDA pre-emption of common-law claims will be "few" or "rare," *ante*, at 502.

JUSTICE O'CONNOR, with whom THE CHIEF JUSTICE, JUSTICE SCALIA, and JUSTICE THOMAS join, concurring in part and dissenting in part.

Section 360k(a), the pre-emption provision of the Medical Device Amendments of 1976 (MDA), provides that no State may establish or continue in effect "any requirement" "which is different from, or in addition to," any requirement applicable under the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) to the device. As the Court points out, because Congress has expressly provided a pre-emption provision, "we need not go beyond that language to determine whether Congress intended the MDA to pre-empt" state law. *Ante,* at 484. We agree, then, on the task before us: to interpret Congress' intent by reading the statute in accordance with its terms. This, however, the Court has failed to do.

The cases require us to determine whether the Lohrs' state common-law claims survive pre-emption under § 360k. I conclude that state common-law damages actions do impose "requirements" and are therefore pre-empted where such requirements would differ from those imposed by the FDCA. The plurality acknowledges that a common-law action might impose a "requirement," but suggests that such a pre-emption would be "rare indeed." *Ante,* at 502. To reach that determination, the opinion—without explicitly relying on Food and Drug Administration (FDA) regulations and without offering any sound basis for why deference would be warranted—imports the FDA regulations interpreting § 360k to "inform" the Court's reading. Accordingly, the principal opinion states that pre-emption occurs only "where a particular state requirement threatens to interfere with a specific federal interest," *ante,* at 500, and for that reason, concludes that common-law claims are almost never pre-empted, *ante,* at 502–503, and that the Lohrs' claims here are not pre-empted. This decision is bewildering and seemingly without guiding principle.

The language of § 360k demonstrates congressional intent that the MDA pre-empt "any requirement" by a State that is "different from, or in addition to," that applicable to the device under the FDCA. The Lohrs have raised various state common-law claims in connection with Medtronic's pacemaker lead. Analysis, therefore, must begin with the question whether state common-law actions can constitute "requirements" within the meaning of § 360k(a).

We recently addressed a similar question in *Cipollone*, where we examined the meaning of the phrase "no requirement or prohibition" under the Public Health Cigarette Smoking Act of 1969. *Cipollone* v. *Liggett Group, Inc.*, 505 U. S. 504 (1992). A majority of the Court agreed that state common-law damages actions do impose "requirements." *Id.*, at 521–522 (plurality opinion); *id.*, at 548–549 (SCALIA, J., joined by THOMAS, J., concurring in judgment in part and dissenting in part). As the plurality explained:

> "The phrase, '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules. As we noted in another context, '[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.' *San Diego Building Trades Council* v. *Garmon*, 359 U. S. 236, 247 (1959)." *Id.*, at 521.

That rationale is equally applicable in the present context. Whether relating to the labeling of cigarettes or the manufacture of medical devices, state common-law damages actions operate to require manufacturers to comply with common-law duties. As *Cipollone* declared, in answer to the same argument raised here that common-law actions

do not impose requirements, "such an analysis is at odds both with the plain words" of the statute and "with the general understanding of common-law damages actions." *Ibid.* If § 360k's language is given its ordinary meaning, it clearly pre-empts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the FDCA—just as it would pre-empt a state statute or regulation that had that effect. JUSTICE BREYER reaches the same conclusion. *Ante,* at 503–505 (opinion concurring in part and concurring in judgment).

The plurality's reasons for departing from this reading are neither clear nor persuasive. It fails to refute the applicability of the reasoning of *Cipollone.* Instead, in Part IV, the plurality essentially makes the case that the statute's language, purpose, and legislative history, as well as the consequences of a different interpretation, indicate that Congress did not intend "requirement" to include state common-law claims at all. The principal opinion proceeds to disclaim this position, however, in Parts V and VI and concludes, rather, that a state common-law action might constitute a requirement, but that such a case would be "rare indeed." *Ante,* at 502. The Court holds that an FDCA "requirement" triggers pre-emption only when a conflict exists between a specific state requirement and a specific FDCA requirement applicable to the particular device. See *ante,* at 498–502. But see *ante,* at 500 ("[W]e do not believe that this statutory and regulatory language necessarily precludes 'general' federal requirements from ever pre-empting state requirements, or 'general' state requirements from ever being pre-empted . . ."). The plurality emphasizes the "critical importance of device specificity" in its understanding of the pre-emption scheme. *Ante,* at 502.

To reach its particularized reading of the statute, the Court imports the interpretation put forth by the FDA's regulations. JUSTICE BREYER similarly relies on the FDA regulations to arrive at an understanding of § 360(k). *Ante,*

at 505–507. Apparently recognizing that *Chevron* deference is unwarranted here, the Court does not admit to deferring to these regulations, but merely permits them to "infor[m]" the Court's interpretation. *Ante,* at 495. It is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference, cf. *Smiley* v. *Citibank (South Dakota), N. A.,* 517 U. S. 735, 743–744 (1996), but one pertaining to the clear statute at issue here is surely not. "If the statute contains an express pre-emption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *CSX Transp., Inc.* v. *Easterwood,* 507 U. S. 658, 664 (1993). Where the language of the statute is clear, resort to the agency's interpretation is improper. See *Chevron U. S. A. Inc.* v. *Natural Resources Defense Council, Inc.,* 467 U. S. 837, 842–843 (1984). Title 21 U. S. C. § 360k(a)(1) directs the pre-emption of "any [state] requirement" "which is different from, or in addition to, any requirement applicable under [the FDCA] to the device." As explained above, and as JUSTICE BREYER agrees, *ante,* at 503–505, the term "requirement" encompasses state common-law causes of action. The Court errs when it employs an agency's narrowing construction of a statute where no such deference is warranted. The statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on "any requirement" exists.

I conclude that a fair reading of § 360k indicates that state common-law claims are pre-empted, as the statute itself states, to the extent that their recognition would impose "any requirement" different from, or in addition to, FDCA requirements applicable to the device. From that premise, I proceed to the question whether FDCA requirements applicable to the device exist here to pre-empt the Lohrs' state-law claims.

I agree with the Court that the Lohrs' defective design claim is not pre-empted by the FDCA's § 510(k) "substantial equivalency" process. The § 510(k) process merely evaluates whether the Class III device at issue is substantially equivalent to a device that was on the market before 1976, the effective date of the MDA; if so, the later device may be also be marketed. Because the § 510(k) process seeks merely to establish whether a pre-1976 device and a post-1976 device are equivalent, and places no "requirements" on a device, the Lohrs' defective design claim is not pre-empted.

I also agree that the Lohrs' claims are not pre-empted by § 360k to the extent that they seek damages for Medtronic's alleged violation of federal requirements. Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is "different from, or in addition to," requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*.

I disagree, however, with the Court's conclusion that the Lohrs' claims survive pre-emption insofar as they would compel Medtronic to comply with requirements different from those imposed by the FDCA. Because I do not subscribe to the Court's reading into § 360k the additional requisite of "specificity," my determination of what claims are pre-empted is broader. Some, if not all, of the Lohrs' common-law claims regarding the manufacturing and labeling of Medtronic's device would compel Medtronic to comply with requirements different from, or in addition to, those required by the FDA. The FDA's Good Manufacturing Practice (GMP) regulations impose comprehensive requirements relating to every aspect of the device-manufacturing process,

including a manufacturer's organization and personnel, buildings, equipment, component controls, production and process controls, packaging and labeling controls, holding, distribution, installation, device evaluation, and recordkeeping. See 21 CFR §§ 820.20–820.198 (1995). The Lohrs' common-law claims regarding manufacture would, if successful, impose state requirements "different from, or in addition to," the GMP requirements, and are therefore pre-empted. In similar fashion, the Lohrs' failure to warn claim is pre-empted by the extensive labeling requirements imposed by the FDA. See, *e. g.*, 21 CFR § 801.109 (1995) (requiring labels to include such information as indications, effects, routes, methods, frequency and duration of administration, relevant hazards, contraindications, side effects, and precautions). These extensive federal manufacturing and labeling requirements are certainly applicable to the device manufactured by Medtronic. Section 360k(a) requires no more specificity than that for pre-emption of state common-law claims.

To summarize, I conclude that § 360k(a)'s term "requirement" encompasses state common-law claims. Because the statutory language does not indicate that a "requirement" must be "specific," either to pre-empt or be pre-empted, I conclude that a state common-law claim is pre-empted if it would impose "any requirement" "which is different from, or in addition to," any requirement applicable to the device under the FDCA. I would affirm the judgment of the Court of Appeals that the Lohrs' design claim is not pre-empted by the MDA, and that the manufacture and failure to warn claims are pre-empted; I would reverse the judgment of the Court of Appeals that the MDA pre-empts a common-law claim alleging violation of federal requirements.